REMARKS

Claims 1-78 are pending in the case. Claims 1-13 and 31-78 have been withdrawn for being drawn to an unelected invention. Claims 14-30 are currently under examination. Claims 14-16 and 27-29 have been amended. Amendment of claims 14 and 27-29 to limit the number of sequences in response to the restriction requirement. No equivalents are surrendered by this amendment. Support for the further amendments to claims 14 and 27-29 can be found, for example, in the last paragraph on page 2 and in claim 27. The amendments to claims 15 and 16 can be found in claim 27. Claim 30 has been cancelled without prejudice. Upon entry of the amendment, claims 14-29 will be pending.

Objections to the Specification

Applicant thanks the Examiner for the careful review of the specification. The specification has been objected to for including the following informalities.

The Office Action notes portions of the specification that include sequences, but do not include SEQ ID NOs. Applicant has amended the specification to insert SEQ ID NOs. As the amendments are simply to point to another portion of the specification, the amendment includes no new matter. No new sequences were entered into the listing.

The Office Action objects to the inclusion of a hyperlink on page 24 of the specification. Applicant has amended the specification to remove the text “http://” which would prevent the URL from acting as a hyperlink. The amendment includes no new matter.

The Office Action objects to the use of a trademark without capitalizing the word or providing generic terminology. XELODA™ is known by the name Capecitabine. The specification has been amended to capitalize XELODA™ and provide the generic terminology. The amendment includes no new matter.

Applicant has amended the specification to correct obvious errors in which Figure 10 is stated to provide a nucleic acid sequence when an amino acid sequence is obviously provided. The amendment includes no new matter.

Applicant submits that the specification is now in proper form.

Objections to the Claims

Claim 15 has been objected to for including an obvious typographical error. The language has been cancelled.

Rejection of the Claims under 35 U.S.C. §112, first paragraph

The Office Action has rejected claims 14-30 for allegedly failing to comply with the written description requirement. The Office Action asserts that the specification does not provide sufficient written description as to the structural features of the claimed genus of polypeptides and the correlation between the chemical structure and function of the genus of polypeptides, such as structural domains or motifs that are essential and distinguish members of the genus from those excluded.

Applicant respectfully disagrees.

The claims have been amended as set forth above to claim a short peptide sequence, up to 12 amino acids, that is at least 60% identical to one of the reference sequences provided. Applicant submits that the claims clearly set forth "structural features" that are essential and distinguish members of the genus from those excluded. Moreover, many of the claims do not include any functional limitations; therefore, no correlation between structure and function is required.

As noted in the Office Action multiple sequence variants are provided in the Sequence Listing, and results from testing such peptides is provided in Table 4. Applicant notes that the peptides in SEQ ID NO: 2, 14, 16, and 19 have at least 90% identity to SEQ ID NO: 1 and peptides in SEQ ID NO: 15, 17, and 18 have at least 80%

identity to SEQ ID NO: 1. Applicant submits that provided with the teachings of the specification, one of skill in the art could readily design polypeptides having at least 60% identity to the amino acid sequence of SEQ ID NO: 1-2 or 14-19.

The Office Action recites that a "representative number of species" of a genus is required to describe the genus. Applicant submits that the specification provides a "representative number of species" and further guidance as to how further design compounds of the invention. In addition to the teachings in the specification pointed to by the Examiner, the specification provides teachings related to mutations that would be expected, or not expected to alter the activity of the peptide, for example in the first full paragraph on page 15 or on page 60.

The Office Action asserts that the specification provides insufficient guidance to one of skill in the art essential for identifying an antagonist polypeptide. Applicant notes that many of the claims are not directed to polypeptides with any specific activity. Moreover, identification of polypeptides that bind HLA molecules with high affinity (e.g., see Example 1) can be performed using flow cytometry, a routine method.

> The test for sufficiency of support under the written description requirement was provided by the Court in *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991), which stated, "Although [the applicant] does not have to describe exactly the subject matter claimed…the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (citations omitted).

Applicants respectfully submit the written description requirement does not necessitate an encyclopedic recounting of all known and yet to be discovered sequences, including variants and alternate isoforms, that might be used in the claimed invention when a generic description is provided. To hold Applicant to this kind of standard is inappropriate and deprives Applicant of protection for the full scope of the claimed invention. Furthermore, Applicant has provided not just a generic description, but has provided multiple operable sequences as discussed above. One of ordinary skill

in the art, armed with the specification would also recognize Applicant to be in possession of the invention as instantly claimed at the time the application was filed.

Applicant notes that the requirement for written description is open ended in that there are no restrictions as to how the specification should describe the invention; instead, it must convey with reasonable clarity to one skilled in the art, that the inventor has captured the invention at the time of filing the application. The specification does this.

Applicants' arguments are strongly supported by Federal Circuit decisions. For example, In *Union Oil Co. v. Atlantic Richfield Co*. 208 F.3d 989, 997 (Fed. Cir. 2000), the court concluded, "A claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language." In accordance with this conclusion, Applicants provide explicit examples of numerous amino acid sequences that do, or do not, have the characteristics in some of the dependent claims. Applicants are NOT required to explicitly describe each and every known or yet to be discovered compound that may or may not fall within the scope of each claim. In fact, the practice of providing each and every sequence is discouraged by both the Patent Office and the court, "the forced recitation of known sequences in patent disclosures would only add unnecessary bulk to the specification" (*Falkner v. Inglis*, No. 05-1324, US Court of Appeals for the Federal Circuit, May 26, 2006).

In addition, the initial burden of proof in establishing whether the claims are supported by an adequate written description falls upon the Examiner, "The description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption" (MPEP 2163.04 and *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971)). Furthermore, the Examiner "must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of the evidence why a person skilled in the art would not recognize in an

applicant's disclosure a description of the invention defined by the claims (*In re Wertheim*, 541 F.2d at 263, 191 USPQ at 97 (CCPA 1976)). The Examiner has not provided sufficient evidence to show that one of skill in the art would not recognize Applicants to be in possession of the full scope of the methods claimed.

Moreover, it is permissible for the claims to include inoperable species. In *National Recovery Technologies, Inc. v. Magnetic Separation Systems, Inc.*,182 the Federal Circuit stated "a claim is not invalid for lack of *operability* simply because the invention does not work perfectly under all conditions." at 1196, 49 U.S.P.Q.2d (BNA) at 1676 (emphasis in original). Provided with the specification, one of skill in the art would understand the inventor to be in possession of a sufficient number of workable embodiments to demonstrate possession of the genus claimed.

The references cited by the Examiner regarding the uncertainty of protein biochemistry are not relevant to peptides having a length of up to 12 amino acids as now claimed. The Office Action states that Skolnick teaches difficulties due to the "multifunctional nature of proteins." The Office Action states that Burgess teaches unpredictability of mutational in studies on acidic FGF, and Lazar teaches the unpredictability of mutational studies on TGFα. Both of these proteins are over 125 amino acids in length, more than ten times the length of the claimed peptides. These references are directed to large proteins, not short peptides as now claimed.

Applicants respectfully submit the subject matter instantly claimed is more than adequately described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors were in possession of the claimed invention at the time the application was filed. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, first paragraph for lack of written description.

Rejection of the Claims under 35 U.S.C. §101

The Office Action has rejected claims 27-30 for being drawn to non-statutory subject matter. Applicant has amended the claims 27-29 to recite an "isolated" polypeptide, indicating the hand of man and directing the claims to statutory subject matter. Withdrawal of the rejection is respectfully requested.

Rejection of the Claims under 35 U.S.C. §102(b)

The Office Action has rejected claims 14-16 for allegedly being anticipated by Gendler et al. (J. Biol. Chem. 265:15286-15293, 1990, hereinafter Gendler). The Office Action alleges that Gendler teaches an amino acid (polypeptide) sequence of mucin 1 which comprises the sequences of SEQ ID Nos. 1, 2, and 14-19, allegedly anticipating the claimed invention.

The Office Action has further rejected claims 14-17 and 20-30 for allegedly being anticipated by Thomson and Ramshaw (WO 01/90197, hereinafter Thomson). The Office Action alleges that Thomson teaches a polypeptide derived from MUC1 that comprises the sequence of SEQ ID No. 1, comprises a sequence that is 90% identical to SEQ ID Nos. 2, 14, 16, and 19 (one amino acid substitution) and comprises a sequence that is 80% identical to SEQ ID Nos. 15, 17, and 19 (two amino acid substitutions).

For the sake of brevity, the rejections will be addressed simultaneously.

The Office Action notes that the claims recite polypeptides that comprise specific sequences. Therefore, the claim language would include full length peptide sequence of Gendler, and the peptide sequences of Thomson.

Without agreeing with the rejection, and purely to progress the prosecution of the application, Applicant has amended the claims to recite polypeptide sequences up to 12 amino acids in length. This is clearly distinct from the cited references that only

teach longer peptide sequences. It is noted that the shortest peptide sequences taught by Thomson are 21 amino acids in length. It would not be obvious in view of Thomson to make the shorter peptides instantly claimed. Withdrawal of the rejection is respectfully requested.

It is believed that the application is now in proper form for allowance. Issuance of a Notice of Allowance is respectfully requested.

Fee Authorization

It is believed that there is no fee due with this response. However, if a fee is due, with this paper or any other paper filed by this firm in relation to this case, the Commissioner is hereby authorized to charge Deposit Account 04-1105 referencing Docket No. 59849(47992). Credit of any overpayment is requested.

Dated: July 9, 2009

Respectfully submitted,

By /Colleen McKiernan/
Colleen McKiernan, Ph.D.
Registration No.: 48,570
EDWARDS ANGELL PALMER & DODGE LLP
P.O. Box 55874
Boston, Massachusetts 02205
617-517-5555
Attorneys/Agents For Applicant